

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

AUROMEDICS PHARMA LLC, and
SCIDOSE LLC,

Plaintiffs,

v.

INGENUS PHARMACEUTICALS, LLC,

Defendant.

C.A. No. 20-1235-CFC-JLH

JOINT CLAIM CONSTRUCTION CHART

Pursuant to the Scheduling Order (D.I. 36), Plaintiffs AuroMedics Pharma LLC and SciDose LLC (together, “Plaintiffs”) and Defendant Ingenuity Pharmaceuticals, LLC (“Defendant”) hereby submit the attached Joint Claim Construction Chart, addressing the parties’ respective claim construction positions concerning U.S. Patent No. 9,662,342 (“the ’342 patent”).

A copy of the ’342 patent is attached hereto as Exhibit 1. A copy of portions of the intrinsic record referred to herein is attached as Exhibit 2. The parties reserve the right to rely on additional intrinsic evidence to the extent it is necessary to provide additional context or to rebut arguments made by any other party during the claim construction briefing. The parties further reserve the right to rely on any intrinsic evidence identified by any other party.

APPENDIX A
Disputed Claim Constructions

No.	Claim Term	Plaintiffs' Proposed Construction and Intrinsic Evidence	Defendant's Proposed Construction and Intrinsic Evidence
1	<p>“an ethanolic solvent system consisting of ethanol”</p> <p>(Claims 1, 2, 4-6, 11-15)</p>	<p>plain and ordinary meaning, <i>i.e.</i>, a solvent from the group of ethanol and its derivatives, consisting of ethanol</p> <p>Intrinsic Evidence: '342 patent at 2:27-30, 2:41-44, 2:49-53; 4:16-25, 5:52-59, tbl. 1, 6:49-52, 7:4-6, tbl. 4, 7:41-67, tbl. 7, cl. 1, cl. 16;</p> <p>Prosecution history of the '342 patent, including originally filed claims (CYCLO_00000008 at -040-042), Response Pursuant to 37 CFR § 1.111 (Sept. 30, 2015) (<i>id.</i> at -081-093), Response to Notice of Non-Compliant Amendment (Oct. 23, 2015) (<i>id.</i> at -101-113), Amendment After Final Rejection (Apr. 12, 2016) (<i>id.</i> at -131-138), Amendment (Sept. 29, 2016) (<i>id.</i> at -157-165), Interview Summary (Oct. 5, 2016) (<i>id.</i> at -169-171), Notice of Allowability (<i>id.</i> at -186-189).</p>	<p>ethanol is the only solvent in the composition</p> <p>Intrinsic Evidence: '342 Patent: Col. 2, ll. 22-30 Col. 2, ll. 49-53 Col. 5, l. 52- Col. 7, l. 30 Col. 7, l. 46-Col. 8, l. 20 Col. 9, l. 22-Col. 10, l. 60 Col. 10, l. 62-Col. 12, l. 38</p> <p>'342 Pros. History: CYCLO00000025-43 CYCLO00000131-138 CYCLO00000145-152 CYCLO00000157-165 CYCLO00000186-189</p> <p>Cited References: U.S. Pat. No. 4,879,286</p>

No.	Claim Term	Plaintiffs' Proposed Construction and Intrinsic Evidence	Defendant's Proposed Construction and Intrinsic Evidence
2	"ethanol soluble acidifying agent" (Claims 1, 2, 4-6, 11-15)	<p>plain and ordinary meaning, <i>i.e.</i>, an acidifying agent that is soluble in ethanol</p> <p><u>Intrinsic Evidence:</u> '342 patent at Abstract, 2:22-26, 2:52-3:7, 3:8-37, 9:12-19, 9:58-61, tbl. 6, cl. 1, cl. 2, cl. 3;</p> <p>Prosecution history of the '342 patent, including originally filed claims (CYCLO_00000008 at -040-042), Response Pursuant to 37 CFR § 1.111 (Sept. 30, 2015) (CYCLO_00000008 at -081-093), Response to Notice of Non-Compliant Amendment (Oct. 23, 2015) (<i>id.</i> at -101-113), Amendment (Sept. 29, 2016) (<i>id.</i> at -157-165).</p>	<p>an ethanol soluble organic acid, inorganic acid or buffer in an amount sufficient to keep the pH of the solution when diluted in IV fluids at 20 mg/ml cyclophosphamide concentration to between about 3 to about 4</p> <p><u>Intrinsic Evidence:</u> <u>'342 Patent:</u></p> <p>Col. 2, l. 54- Col. 3, l. 8 Col. 3, ll. 9-38 Col. 8, l. 23-Col. 9, l.15 Col. 9, ll. 21-61 Col. 10, ll. 5-23 Col. 10, ll. 26-60</p> <p><u>Cited References:</u></p> <p>Gillard et al., "Chemical and Biological Evaluation of Hydrolysis Products of Cyclophosphamide," <i>J. Med. Chem.</i> 1994, 37, 3986-3993</p>
3	"acidifying" (Claims 1, 2, 4-6, 11-15)	<p>does not need separate construction from "ethanol soluble acidifying agent;" to the extent construction is necessary, plain and ordinary meaning, <i>i.e.</i>, to reduce pH</p>	<p>reducing pH in an acidic range</p> <p><u>Intrinsic Evidence:</u> <u>'342 Patent:</u></p>

No.	Claim Term	Plaintiffs' Proposed Construction and Intrinsic Evidence	Defendant's Proposed Construction and Intrinsic Evidence
		<p><u>Intrinsic Evidence:</u> '342 patent at Abstract, 2:22-26, 2:52-3-7, 3:8-37, 9:12-19, 9:58-61, tbl. 6, cl. 1, cl. 2; cl. 3;</p> <p>Prosecution history of the '342 patent, including originally filed claims (CYCLO_00000008 at -040-042), Response Pursuant to 37 CFR § 1.111 (Sept. 30, 2015) (CYCLO_00000008 at -081-093), Response to Notice of Non-Compliant Amendment (Oct. 23, 2015) (<i>id.</i> at -101-113), Amendment (Sept. 29, 2016) (<i>id.</i> at -157-165).</p>	<p>Col. 2, ll. 54-56 Col. 3, ll. 2-7 Col. 8, l. 23- Col. 9, l. 15</p> <p><u>Cited References:</u> Gilard et al., “<i>Chemical and Biological Evaluation of Hydrolysis Products of Cyclophosphamide</i>,” J. Med. Chem. 1994, 37, 3986-3993</p>
4	“wherein the cyclophosphamide and the ethanol soluble acidifying agent are solubilized in the ethanol” (Claims 1, 2, 4-6, 11-15)	<p>plain and ordinary meaning, <i>i.e.</i>, cyclophosphamide and ethanol soluble acidifying agent are solubilized in the ethanol</p> <p><u>Intrinsic Evidence:</u> '342 patent at 2:17-26, 4:16-25, 7:46-56, 9:12-19; cl. 1; cl. 16</p> <p>Prosecution history of the '342 patent, including Response Pursuant to 37 CFR § 1.111 (Sept. 30, 2015) (CYCLO_00000008 at -081-093), Response to Notice of Non-Compliant Amendment (Oct. 23, 2015) (<i>id.</i> at -101-113); Amendment (Sept. 29, 2016) (<i>id.</i> at -157-165).</p>	<p>both the cyclophosphamide and the ethanol soluble acidifying agent are completely dissolved in the ethanol</p> <p><u>Intrinsic Evidence:</u> '342 Pros. History: CYCLO00000157-165</p>

No.	Claim Term	Plaintiffs' Proposed Construction and Intrinsic Evidence	Defendant's Proposed Construction and Intrinsic Evidence
5	“extended stability” (Claims 1, 2, 4-6, 11-15)	<p>Not indefinite; maintain high levels of cyclophosphamide content (<i>i.e.</i>, a loss of potency of no more than about 3-5%) after about 18 months at a temperature of about 5° C</p> <p>Intrinsic Evidence: '342 patent at Abstract, 2:16-26, 2:35-37, 3:51-63, 4:4-10, 5:36-45, 5:52-59, tbls. 1-3, 6:53-7:6, tbl. 4, 7:32-37, 7:57-8:4, tbl. 5, 8:23-9:21, tbl. 6, 10:1-3, tbl. 7, 10:19-29, tbl. 8, cl. 1, cl. 14, cl. 15;</p> <p>Prosecution history of the '342 patent, including originally filed claims (CYCLO_00000008 at -040-042), Response Pursuant to 37 CFR § 1.111 (Sept. 30, 2015) (CYCLO_00000008 at -081-093), Response to Notice of Non-Compliant Amendment (Oct. 23, 2015) (<i>id.</i> at -101-113), Amendment (Sept. 29, 2016) (<i>id.</i> at -157-165).</p>	<p>Indefinite</p> <p>Intrinsic Evidence: <u>'342 Patent:</u></p> <p>Col. 2, ll. 22-24; ll. 35-37 Col. 4, ll. 6-10 Col. 6, ll. 54-59 Col. 6, l. 64-Col. 7, l. 37 Col. 7, l. 46-Col. 8, l. 20 Tables 4-8 Col. 9, ll. 20-62 Col. 10, ll. 1-24</p>
6	“substantially non-aqueous” (Claims 1, 2, 4-6, 11-15)	<p>Not indefinite; plain and ordinary meaning, <i>i.e.</i>, does not contain a substantial amount of water</p> <p>Intrinsic Evidence: '342 patent at 2:27-30, 2:41-48, 3:58-62, 4:16-25, tbl. 1, 6:47-53, tbl. 4, 7:40-8:4, 9:15-19, tbl. 6, 9:62-67, cl. 1-19;</p> <p>Prosecution history of the '342 patent, including Amendment (Sept. 29, 2016) (CYCLO_00000008</p>	<p>Indefinite</p> <p>Intrinsic Evidence: <u>'342 Patent:</u></p> <p>Col. 1, ll. 40-48 Col. 2, ll. 41-53 Col. 3, ll. 58-62 Col. 4, ll. 30-45 Col. 6, l. 47 – Col. 7, l. 6</p>

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		at -157-165), Notice of Allowability (<i>id.</i> at -186-189).	Col. 7, l. 41-Col. 8, l. 20 Col. 9, l. 15-67 Col. 10, ll. 26-60 Tables 5-8 <u>‘342 Pros. History:</u> CYCLO00000157-165 CYCLO00000186-189

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